K093588

AMERICAN RADIOSURGERY

JAN 11 2010

5. 510(k) Summary

Submitter/Applicant Name:	American Radiosurgery, Inc.
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Date prepared:	October 30, 2009
Trade name:	Explorer 4D™ Treatment Planning System
Common name:	Radiation Therapy Treatment Planning System
Classification name:	System, Planning, Radiation Therapy Treatment
Classification:	21 CFR Part 892.5050 Class II

Substantial equivalence claimed to:
The Explorer 4D™ Treatment Planning System is functionally and substantially equivalent to the Explorer 3D but hosted on a new hardware platform. Both systems include functionality for Dose Volume Histograms, visualization of dose shots, selection of skin boundary, phantom calibration, automated dose calculations, and the same collimator sizes. Performance for both systems is spatial accuracy of 1 mm and accuracy of dose delivery is 3%. New features in the Explorer 4D™ Treatment Planning System include automated skin boundary selection and an enhanced fiducial marker input and detection scheme.

Description
The Explorer 4D™ Treatment Planning System (TPS) provides individual treatment plans for patients undergoing gamma radiation therapy treatment. The TPS provides for the import of patient images and selecting a series of relevant patient images to create a treatment plan.

Precise calculation of the dose delivery parameters is supported by the registration of fiducial markers as a reference point between patient images. These images are then annotated with the region of interest (ROI) to be exposed to radiation. Several tools are provided to adjust the ROI based on the desired treatment area, within these regions "shots" (radiation sources) and associated treatment dose levels are defined as they related to a specified collimator size.

When the plan definition is completed the operator can save or export the treatment plan.

Performance
The Explorer 4D™ Treatment Planning System Performance Test Report (Attachment 10) provides data from ten separate performance tests demonstrating the dose delivery and spatial accuracy of the Explorer 4D™ Treatment Planning System.

Intended Use
The Explorer 4D™ Treatment Planning System software is intended for use in preparing treatment plans for patients who have intracranial diseases where neurological radio surgery has been prescribed.

The software is used to electronically import CT images to determine the precise location of the target, to define and visualize treatment beam locations, and to visualize dose to the target and other structures.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

American Radiosurgery, Inc.
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

JAN 11 2010

Re: K093588
Trade/Device Name: Explorer 4D™ Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: December 29, 2009
Received: December 31, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number: K093588 (To be determined)
Device Name: Explorer 4D™ Treatment Planning System

Indications for Use:

The Explorer 4D™ Treatment Planning System software is intended for use in preparing treatment plans for patients who have intracranial diseases where neurological radio surgery has been prescribed.

The software is used to electronically import CT images to determine the precise location of the target, to define and visualize treatment beam locations, and to visualize dose to the target and other structures.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093588